FDA 510(k) Premarket Notification

K211191 Virtual C DRF Digital Imaging System

CLEARED

Jun 24, 2021
64 days to decision

K211191 · Product code: **OWB** · Radiology
Source: https://www.510kdatabase.net/k211191/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Apr 21, 2021
Decision date	Jun 24, 2021
Days to decision	64 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Portavision Medical, LLC**
Location	Kenner, LA, US
Contact	Terry Ancar
510(k) history	5 submissions · 5 cleared · 2008-2021

REGULATORY CONSULTANT

Consulting firm	**Kamm and Associates**
Contact	Daniel Kamm

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov